REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Amendments to the Specification and Claims

In the specification, the Title has been amended to better reflect the subject matter of the application. This amendment to the specification does not include new matter.

This amendment also adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Claims 63, 67, and 68 are currently being amended to further prosecution. Claims 75-77 are requested to be added. Support for the amended and new claims is provided in the original claims and specification as filed. For example, support for amended claim 63 is provided in the original claims and further at paragraphs [0020], [0027]-[0028], [0049], and [0050]-[0052] (providing a definition for "fragment"), and paragraphs [0024]-[0025] (providing a definition for "variant"). Support for new claim 77 is provided in the original claims and further at paragraphs [0035]-[0037].

The amendments to the claims do not add new matter and are requested to be entered. After amending the claims as set forth above, claims 63-77 are now pending in this application. Claims 70 and 71 currently are withdrawn from consideration in view of the Examiner's restriction requirement.

II. Objection - Title

The Examiner objected to the title of the application as not being descriptive. The Examiner suggested that the title be amended to recite "antibodies to a chemokine expressed in inflamed adenoid." The title has been amended accordingly. Withdrawal of the ground for objection is requested.

III. Rejection - 35 U.S.C. § 112, first paragraph "new matter"

Claims 63-66 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Applicants traverse the rejection in view of the foregoing amendments and for the following reasons.

Claim 63 was rejected for reciting the following phrases: "polypeptide consisting essentially of the amino acid sequence of"; "polypeptide consisting essentially of naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:2"; and "fragment consisting essentially of at least 9 contiguous amino acids of a polypeptide consisting of the amino acid sequence of SEQ ID NO:2." As amended, claim 63 does not recite these phrases.

With respect to recitation of "fragment of SEQ ID NO:2 including at least 10 contiguous amino acids," support is provided for example at paragraph [0051] (reciting that "ADEC for antibody induction does not need to have biological activity; however, it must be immunogenic" and "Peptides used to induce ADEC specific antibodies may have an aa sequence consisting of at least five aa, ***preferably at least 10 aa***"). This is not new matter.

Claim 63 also was rejected for reciting the phrase "human antibody" allegedly because the phrase "human antibody" is new matter. Applicants respectfully disagree that the phrase "human antibody" is new matter because human antibodies are contemplated by the present specification. First, it is respectfully noted that "[t]he subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the written description requirement." *See* MPEP § 2163.02. The specification indicates that "[a]ntibodies specific for ADEC may be produced by inoculation of an appropriate animal with the polypeptide or an antigenic fragment." *See* U.S. 2004-0086975, paragraph [0052]. One of skill in the art would recognize that an appropriate animal may include a human.

Further, the specification indicates that antibodies to ADEC may include human monoclonal antibodies obtained from human hybridomas. The specification states:

> Hybridomas may also be prepared and screened using standard techniques.....***Monoclonal antibodies*** with affinities of at least 10^8 M^{-1}, preferably 10^9 to 10^{10} or stronger, ***will typically be made by standard procedures as described in Harlow and Lane (1988) Antibodies: A Laboratory Manual, Cold Spring Harbor Laboratory, N.Y.***; and in Goding (1986) Monoclonal Antibodies: Principles and Practice, 2nd Ed, Academic Press, New York, N.Y.; both ***incorporated herein by reference***.

See id., paragraph [0085] (emphasis added). Harlow and Lane, which is incorporated in the specification by reference, specifically discloses human hybridomas and human monoclonal antibodies stating:

> One of the most exciting areas for hybridoma research over the last 5 years has been the development of systems for the production of ***human hybridomas. Human monoclonal antibodies will be used extensively for clinical applications***.

See Harlow and Lane (1988) Antibodies: A Laboratory Manual, Cold Spring Harbor Laboratory, N.Y., pages 241-243 [EXHIBIT 1]. Continuing, Harlow and Lane describes various systems for producing human hybridomas. *See id.* Therefore, the specification indicates that antibodies of the invention may include human antibodies.

The specification also indicates that "recombinant immunoglobulins may be produced as shown in U.S. Pat. No. 4,816,567, incorporated herein by reference." *See* U.S. 2004-0086975, paragraph [0088]. As indicated in U.S. Pat. No. 4,816,567 [EXHIBIT 2], recombinant immunoglobulins may be prepared from human monoclonal antibodies. *See, e.g.*, U.S. Pat. No. 4,816,567, col. 2, lines 7-13 (stating that "[h]ybridoma technology has to this time been focused largely on the fusion of murine lines, but ***human-human*** hybridomas [and] ***human-murine*** hybridomas...have been prepared as well" (emphasis added, citations omitted)); col. 14, lines 44-56 (discussing the use of "components of 'natural' antibodies" which may be derived from "***human-murine hybridomas***" (emphasis added)); and col. 16, lines 1-8 (discussing the use of portions of "***human antibodies*** recovered and cloned from, for example, ***human myeloma cells***" (emphasis added)).

In addition, the specification states:

> Frequently, the polypeptides and ***antibodies will be labeled*** by joining them, either covalently or noncovalently, with a substance which provides for a detectable signal. ***A wide variety of labels and conjugation techniques are known and have been reported extensively in both the scientific and patent literature.*** Suitable labels include radionuclides, enzymes, substrates, cofactors, inhibitors, fluorescent agents, chemiluminescent agents, magnetic particles and the like. ***Patents teaching the use of such labels include U.S. Pat. Nos. 3,817,837; 3,850,752; 3,939,350; 3,996,345; 4,277,437; 4,275,149; and 4,366,241.***

See U.S. 2004-0086975, paragraph [0088]. As such, the specification indicates that the antibodies of the invention may be labeled using methods described, for example, in U.S. Pat. Nos. 3,996,345; 4,275,149; and 4,277,437 [EXHIBITS 3, 4, and 5, respectively]. These patents provide explicit support for labeled human antibodies. For example, these patent describe labeling human IgG with fluorescein (see U.S. Pat. No. 3,996,345, col. 28, EXAMPLE V); labeling human IgG with horseradish peroxidase (see U.S. Pat. No. 4,277,437, col. 19, EXAMPLE 1); labeling human IgG with glucose-6-phosphate dehydrogenase (see U.S. Pat. No. 4,275,149, col. 36, EXAMPLE 1); labeling human IgG with β-D-galactosidase (see U.S. Pat. No. 4,275,149, col. 38, EXAMPLE 7); and labeling of human IgG with β-galactosidase (see U.S. Pat. No. 4,275,149, col. 39 EXAMPLE 9). This indicates that labeled human antibodies are contemplated by the specification.

Clearly, the specification contemplates and provides support for "human antibodies" as would be recognized by one of skill in the art. For all these reasons, the recitation of "human antibodies" is not new matter. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, for alleged "new matter" are requested.

IV. Rejection - 35 U.S.C. § 112, first paragraph, "written description"

Claims 63-69 and 72-74 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly "failing to comply with the written description requirement." The Examiner asserted that "the written description is not commensurate in scope with the claims drawn to

an antibody to 'a naturally occurring amino acid sequence at least 90% identical to...SEQ ID NO:2' as recited in claim 11(b) [sic]." The claims have been amended and do not recite "at least 90% identical to SEQ ID NO:2." For these reasons, withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, for inadequate written description is requested.

V. Rejection - 35 U.S.C. § 112, first paragraph, "enablement"

Claims 63-69 and 72-74 were rejected under 35 U.S.C. § 112, first paragraph, allegedly "because the specification, while being enabling for an isolated antibody which specifically binds a protein consisting of the amino acid sequence set forth in SEQ ID NO:2 does not reasonably provide enablement for an isolated antibody to a protein consisting essentially of a naturally occurring amino acid sequence at least 90% identical to SEQ ID NO:2." The Examiner also asserted that "the specification does not enable an antibody to a protein 'consisting essentially of' the amino acid sequence set forth in SEQ ID NO:2." Further, the Examiner asserted that the claims were non-enabled with respect to the recitation of "fragment."

Applicants thank the Examiner for indicating that the specification is enabling for "an isolated antibody which specifically binds a protein consisting of the amino acid sequence set forth in SEQ ID NO:2." As amended, the claims do not recite "at least 90% identical to SEQ ID NO:2," or "consisting essentially of."

With respect to recitation of "polypeptide comprising...a fragment of SEQ ID NO:2 including at least 10 contiguous amino acids," one would not have to undergo undue experimentation to make and use the subject matter of the claim. First, the recited polypeptide comprises a fragment of SEQ ID NO:2 that includes "at least ***10 contiguous amino acids***." The full-length sequence of SEQ ID NO:2 is only 109 amino acids, so the possible number of fragments in the recited polypeptide is not large.

Further, the polypeptide must have "chemotactic activity" or "activate neutrophils or monocytes." The specification provides methods for "Determination of ADEC-Induced Chemotaxis or Cell Activation" (see paragraphs [0093]-[0100]), which methods further are

known in the art. Therefore, one of skill in the art has a method for testing the recited subject matter.

In addition, the specification provides guidance as to what portions of SEQ ID NO:2 may be necessary or sufficient for activity. For example, the specification provides an alignment of SEQ ID NO:2 with other human chemokines of the C-X-C family at Figure 2. This provides guidance as to which amino acids of SEQ ID NO:2 are conserved among human C-X-C chemokines and may be necessary or sufficient for activity. All of the chemokines in Figure 2 have a leucine-rich region (see, e.g., aa 8-13 of SEQ ID NO:2). All of the cytokines in Figure 2 include a C-X-C motif (see, e.g., aa 33-35 of SEQ ID NO:2). These conserved regions as well as many other conserved amino acids serve as "guideposts" for identifying portions that are necessary or sufficient for biological activity.

In addition to the alignment at Figure 2, the specification provides a hydrophilicity plot and an antigenic index plot at Figure 4. This provides even further guidance as to which portions of SEQ ID NO:2 may be necessary and sufficient for biological activity.

Based on this information, one of skill in the art could select portions of SEQ ID NO:2 and test them using methods disclosed in the specification or known in the art to identify those portions having biological activity. For example, one skilled in the art could synthesize chimeras of SEQ ID NO:2 and the other human chemokines of the C-X-C family, exchanging conserved or non-conserved regions, in order to identify portions of SEQ ID NO:2 that are necessary or sufficient for activity. None of these methods would require undue experimentation because one of skill in the art has been provided with all the necessary tools and information for performing the methods.

For these reasons, withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement is requested.

VI. Rejection - 35 U.S.C. § 112, second paragraph

Claims 63-69 and 72-74 were rejected under 35 U.S.C. § 112, second paragraph, as being allegedly "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." In particular, claim 63 was rejected for reciting the phrases "consisting essentially of amino acid sequence," "naturally occurring," and "is able to activate neutrophils or monocytes." As amended, claim 63 does not recite these phrases.

Claim 63 and claim 67 were rejected for including typographical errors. The typographical errors have been corrected. For these reasons, withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is requested.

VII. Rejection - 35 U.S.C. § 102

Claims 63, 66, and 67 were rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Osawa *et al.* (U.S. Pat. No. 5,126,434) [hereinafter "Osawa"]. Applicants respectfully traverse the rejection.

Osawa discloses a monoclonal antibody to a peptide having the amino acid sequence [Trp,Arg]-Leu-Gly-Arg-[Glu,Gln]-Asp-Gly-Ser-Glu. This amino acid sequence is not present in SEQ ID NO:2. Therefore, Osawa does not teach or suggest an antibody as recited in the present claims. For these reasons, withdrawal of the rejection under 35 U.S.C. § 102(b) is requested.

VIII. Rejection - 35 U.S.C. § 103

Claims 63, and 66-69 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Osawa as applied to claims 63, 66, and 67 above, and further in view of Hart (U.S. Pat. No. 5,094,941) [hereinafter "Hart"]. Applicants respectfully traverse the rejection.

As indicated above, Osawa discloses a monoclonal antibody to a peptide having the amino acid sequence [Trp,Arg]-Leu-Gly-Arg-[Glu,Gln]-Asp-Gly-Ser-Glu. This amino acid sequence is not present in SEQ ID NO:2. Therefore, Osawa does not teach or suggest an antibody as recited in the present claims. For these reasons, the claims are not obvious in view of Osawa alone or further in view of Hart. Withdrawal of the rejection under 35 U.S.C. § 103(a) is requested.

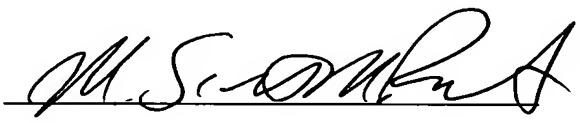
IX. Conclusion

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date March 13, 2006

By 

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